



## **Agricultural Marketing Service**

### **7 CFR Part 205**

**[Doc. No. AMS-NOP-19-0053; NOP-19-02]**

**RIN 0581-AD92**

## **National Organic Program: Amendments to the National List of Allowed and Prohibited Substances per April 2019 NOSB Recommendations (Livestock and Handling)**

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** This rule amends the National List of Allowed and Prohibited Substances (National List) section of the U.S. Department of Agriculture's (USDA) organic regulations to implement recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB). This rule adds the following allowed substances to the National List: oxalic acid dihydrate as a pesticide for organic apiculture (beekeeping); pullulan for use in organic handling in products labeled, "Made with organic (specified ingredients or food group(s));" and collagen gel as a nonorganic nonagricultural substance for use as a casing in organic handling when organic forms of collagen gel are not commercially available.

**DATES:** This rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Jared Clark, Standards Division, National Organic Program. Telephone: (202) 720-3252.

### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

On December 21, 2000, the Secretary established the Agricultural Marketing Service's (AMS) National Organic Program and the USDA organic regulations (65 FR 80547). Within the USDA organic regulations (7 CFR Part 205) is the National List of Allowed and Prohibited Substances (or National List). The National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic crop and livestock production. It also identifies the nonorganic substances that may be used in or on processed organic products.

AMS is finalizing three amendments to the National List in accordance with the procedures detailed in the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501–6524). OFPA establishes what may be included on the National List and the procedures that USDA must follow to amend the National List (sec. 6517). OFPA also describes the NOSB's responsibilities in proposing amendments to the National List, including the criteria for evaluating amendments to the National List (sec. 6518).

This final rule adds oxalic acid dihydrate, pullulan, and nonorganic collagen gel to the National List. Once effective, producers and handlers of organic products will be allowed to use these substances in organic production and in organic products. The permitted use of each substance is discussed in detail below.

To remain on the National List, these substances must be: (1) reviewed every 5 years by the NOSB, a 15-member federal advisory committee; and (2) renewed by the Secretary (sec. 6517(e)). This action of NOSB review and USDA renewal is commonly referred to as the "sunset review" or "sunset process." AMS published information about this process in the **Federal Register** on September 16, 2013 (78 FR 56811). The sunset date (i.e., the date by which the Secretary must renew a substance for the listing to remain valid on the National List) for each substance is included in the NOP Program Handbook (document NOP 5611). The first sunset date for the substances in this final rule will be 5 years from the effective date in the DATES section of this final rule above.

## II. Overview of Amendments

This rule adds oxalic acid, pullulan, and nonorganic collagen gel to the National List for use in organic livestock production or handling. Additional background on the petitions and the NOSB's review of the substances may be found in the proposed rule (85 FR 35011; June 8, 2020).

During a 60-day comment period that closed on August 7, 2020, AMS received 20 comments on the proposed rule. See below for a discussion of the comments received and AMS' responses to comments. Comments can be viewed through Regulations.gov. Use the search area on the homepage at <https://www.regulations.gov> to enter a keyword, title, or docket ID (the docket folder for this rule is AMS-NOP-19-0053).

### **Oxalic acid dihydrate (§ 205.603)**

#### **Final action**

The final rule amends the National List to add oxalic acid dihydrate to 7 CFR 205.603 as a synthetic substance allowed for use in organic apiculture (beekeeping) only. Oxalic acid dihydrate is a pesticide used for *Varroa* mite control on bees. Oxalic acid is a naturally occurring substance, but this rule allows for the use of the synthetic form (i.e., synthesized via chemical process) of oxalic acid dihydrate.

AMS is finalizing this amendment to the National List, as proposed by NOSB, to provide beekeepers that manage organic bees with an additional option to combat parasitic *Varroa* mites. Since arriving to the United States in 1987, *Varroa* mites have caused the death of massive numbers of honey bee colonies, and beekeepers have identified *Varroa* mites as their single most serious problem causing colony losses.<sup>1</sup> The mites damage honey bees both directly (by attaching to bees) and by serving as a vector for pathogenic viruses.

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<sup>1</sup> USDA Agricultural Research Service <https://www.ars.usda.gov/oc/br/ccd/index/>. Accessed February 1, 2021.

Oxalic acid dihydrate is one of a dozen substances currently registered by the EPA for the control of *Varroa* mites,<sup>2</sup> and only a subset of these are allowed under USDA organic regulations. For example, the National List includes formic acid (§ 205.603(b)(3)) as a pesticide to treat hives. The addition of oxalic acid dihydrate will be an important addition to the National List, as rotating products to combat *Varroa* mites is an important tactic to prevent resistance development and to maintain the usefulness of individual pesticides.<sup>3</sup>

AMS concluded that the addition of oxalic acid dihydrate to the National List is consistent with the requirements of OFPA sec. 2118(c) (7 USC 6517(c)). Namely, the substance is not harmful to human health or the environment when used as labeled; is necessary to production because of the unavailability of wholly natural substitute products; and is consistent with organic farming and handling. The amendment is made following the procedures established in section 2118(d) of the OFPA (7 USC 6517(d)).

#### **NOSB review and recommendation (oxalic acid dihydrate)**

NOSB submitted a recommendation to AMS in April 2019 to add oxalic acid dihydrate to the National List.<sup>4</sup> NOSB recommendation followed receipt of a petition to add the substance to the National List in October 2017.<sup>5</sup> In NOSB's evaluation of the petition, they considered information from a third-party technical evaluation report<sup>6</sup> and comments from the public. NOSB discussed the petition to amend the National List in subcommittee calls and at its public meetings in October 2018 and April 2019.<sup>7</sup>

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<sup>2</sup> U.S. Environmental Protection Agency, <https://www.epa.gov/pollinator-protection/epa-registered-pesticide-products-approved-use-against-varroa-mites-bee-hives>. Accessed February 1, 2021.

<sup>3</sup> U.S. Environmental Protection Agency, <https://www.epa.gov/pollinator-protection/epa-registered-pesticide-products-approved-use-against-varroa-mites-bee-hives>. Accessed February 1, 2021.

<sup>4</sup> NOSB final recommendation for oxalic acid **dihydrate**, **April 26, 2019**:

<https://www.ams.usda.gov/sites/default/files/media/LSOxalicAcidApril2019FinalRec.pdf>.

<sup>5</sup> Oxalic acid petition:

<https://www.ams.usda.gov/sites/default/files/media/OxalicAcidPetition10032017.pdf>.

<sup>6</sup> Technical Evaluation Report for oxalic acid **dihydrate**, **November 26, 2018**:

<https://www.ams.usda.gov/sites/default/files/media/OxalicAcidTR.pdf>.

<sup>7</sup> Written and oral public comments submitted for the October 2018 and April 2019 NOSB meetings are available at <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-st-paul-mn> and <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-seattle-wa>.

In its recommendation, NOSB concluded that adding oxalic acid dihydrate to the National List was consistent with OFPA evaluation criteria in section 2119(m) (7 USC 6518(m)). NOSB found that the use of oxalic acid dihydrate as a mite pest control would be compatible with and necessary for organic apiculture, providing additional use benefits over formic acid. NOSB noted that oxalic acid occurs naturally in the environment and noted no concerns about environmental or human health impacts or oxalic acid residues in food products.

### **Comments received and AMS' response (oxalic acid dihydrate)**

*Apiculture standards.* Comments recommended that AMS act on NOSB recommendations from September 2001 and October 2010<sup>8</sup> to further develop organic apiculture standards. Some believed that AMS should promulgate detailed standards for managing organic bees prior to adding synthetic substances for organic apiculture to the National List.

AMS notes that the USDA organic regulations include “nonplant life” (e.g., bees) in the definition of livestock (§ 205.2). Given that AMS permits USDA-accredited certifiers to certify organic apicultural operations under the regulations for livestock production, AMS will continue to consider recommendations from NOSB regarding substances for organic apiculture operations. Additionally, the National List includes other substances that may be used in organic apiculture, including formic acid (§ 205.603(b)(3)), which is permitted for the treatment of honeybee hives. Oxalic acid dihydrate provides some advantages compared to formic acid, and AMS is adding the substance to the National List to provide certified organic apiculture operations with an additional option to treat for *Varroa*.

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<sup>8</sup> NOSB Apiculture Task Force Report, September 2001: <https://www.ams.usda.gov/sites/default/files/media/Rec%20Apiculture%20Standards.pdf>; and NOSB's Apiculture Recommendation, October 2010: <https://www.ams.usda.gov/sites/default/files/media/NOP%20Livestock%20Final%20Rec%20Apiculture.pdf>.

*General opposition.* Some comments opposed the addition of oxalic acid dihydrate to the National List because they opposed any use of synthetic substances in organic production. AMS notes that OFPA permits the use of specific synthetic substances (i.e., those on the National List) in organic production. OFPA describes the procedures for amending the National List and provides AMS and the NOSB with criteria and guidelines to consider in evaluating changes to the National List. NOSB and AMS followed these procedures, and this rule adds oxalic acid dihydrate to the National List.

*Health effects.* Finally, AMS received a comment opposing the addition of oxalic acid dihydrate that cites a source that suggests that the consumption of oxalic acid dihydrate inhibits calcium availability in the human body. AMS does not find merit in the comment. AMS notes that EPA’s Final Registration Decision for oxalic acid states this compound is only used in beehives when honey supers are not present and that dietary exposures to oxalic acid from in-hive applications is indistinguishable from naturally occurring levels.<sup>9</sup>

## **Pullulan (§ 205.605)**

### **Final action**

This final rule amends the National List to add pullulan to § 205.605(a) as an ingredient allowed only in products labeled, “Made with organic (specified ingredients or food group(s))” (or “made with”). The “made with” labeling category is distinct from the “organic” and “100% organic” labeling categories under USDA organic regulations (7 CFR 205.301). Products labeled “organic” or “100% organic” cannot contain nonorganic pullulan as an ingredient under this final rule. Additionally, the final rule only permits nonorganic pullulan in tablets and capsules for dietary supplements.

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<sup>9</sup> U.S. Environmental Protection Agency, Registration Decision for the New Active Ingredient Oxalic Acid, March 2015, <https://www.regulations.gov/document?D=EPA-HQ-OPP-2015-0043-0119>. Accessed February 1, 2021.

AMS is finalizing this amendment to the National List, as proposed by NOSB, to add pullulan to the National List for use in “made with” products to provide manufacturers of organic dietary supplements with an option to label products with additional dietary claims (e.g. vegan, vegetarian). Nonorganic forms of pullulan are necessary because organic forms of pullulan are not readily available. By adding nonorganic pullulan to § 205.605 of the National List with a limitation on use for “made with” products, AMS is providing a limited exception for use of nonorganic pullulan.

Pullulan is a natural extracellular polysaccharide excretion resulting from carbohydrate fermentation by the yeast-like fungus *Aureobasidium pullulans* and other non-toxic fungi strains.<sup>10</sup> The fungus *A. pullulans* is ubiquitous in nature and is most common in temperate zones in locations such as forest soil, freshwater, on plant leaves, and on seeds. Pullulan has been self-affirmed as GRAS (Generally Recognized as Safe) for multiple uses, including as a multifunctional food ingredient, a film, and an excipient (GRN No. 99, pp. 26 – 30).<sup>11</sup>

AMS concluded that the addition of pullulan to the National List is consistent with the requirements of OFPA sec. 6517(c). Namely, the substance is not harmful to human health or the environment; is necessary to production because of the unavailability of wholly natural substitute products; and is consistent with organic farming and handling. The amendment is made following the procedures established in OFPA (sec. 6517(d)).

#### **NOSB review and recommendation (pullulan)**

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<sup>10</sup> Pullulan technical evaluation report, September 7, 2018: <https://www.ams.usda.gov/sites/default/files/media/PullulanTechnicalReportFinal09072018.pdf>. Accessed February 1, 2021.

<sup>11</sup> GRAS Notice (GRN) No. 99 and FDA’s response to the Notice, are available at: <https://www.fda.gov/food/generally-recognized-safe-gras/gras-notice-inventory>. Accessed February 1, 2021.

NOSB submitted a recommendation to AMS in April 2019 to add pullulan to the National List.<sup>12</sup> NOSB recommendation followed receipt of a petition to add the substance to the National List in January 2018.<sup>13</sup> In NOSB's evaluation of the petition, they considered information from a third-party technical evaluation report<sup>14</sup> and comments from the public. NOSB discussed the petition to amend the National List in subcommittee calls and at its public meetings in October 2018 and April 2019.<sup>15</sup>

In its recommendation, NOSB concluded that adding pullulan to the National List was consistent with OFPA criteria (sec. 6518(m)). In its recommendation, NOSB noted that there are few, if any, other encapsulation options available compliant with organic composition requirements at § 205.301 for consumers seeking a suitable alternative to gelatin for religious and dietary requirements (e.g., vegan, halal, kosher).

#### **Comments received and AMS' response (pullulan)**

*Classification.* In the proposed rule, AMS requested comments on whether pullulan should be classified as a nonsynthetic, nonagricultural substance, as proposed, or whether it should be considered as an agricultural substance that may be certifiable as organic.

An opposing comment argued that production of pullulan should be considered a form of agricultural production and compared production of *A. pullulans* to other types of fungi production. The comment suggested that pullulan is better described as an agricultural product than a nonagricultural product.

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<sup>12</sup> NOSB final recommendation for pullulan, April 26, 2019:

<https://www.ams.usda.gov/sites/default/files/media/HSPullulanApr2019FinalRec.pdf>.

<sup>13</sup> Pullulan petition: <https://www.ams.usda.gov/sites/default/files/media/PullulanPetition18131.pdf>.

<sup>14</sup> Pullulan technical evaluation report, September 7, 2018:

<https://www.ams.usda.gov/sites/default/files/media/PullulanTechnicalReportFinal09072018.pdf>.

<sup>15</sup> Written and oral public comments submitted for the October 2018 and April 2019 NOSB meetings are available at <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-st-paul-mn> and <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-seattle-wa>.

AMS also received comments that agreed with the classification of pullulan as nonagricultural. Comments that argued that pullulan is a nonsynthetic state that other products of microbial fermentation at § 205.605(a) (e.g., citric acid, enzymes, microorganisms) are classified as nonsynthetic.

AMS received several comments that AMS' classification of pullulan as nonagricultural does not mean that pullulan cannot also be certified organic (i.e., that pullulan could be certified organic if manufactured by alternative processes). Commenters pointed to published AMS guidance and to examples of other substances on the National List at § 205.605 that can be found in certified organic form (e.g., yeast, flavors, citric acid).

AMS agrees with the classification of pullulan as nonsynthetic. The referenced guidance<sup>16</sup> provides examples and clarity on the definitions of “agricultural,” “synthetic,” and “nonsynthetic (natural)” as presented in § 205.2. Nonsynthetic substances are defined as “A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process ...”. Given that pullulan is manufactured by the isolation of a byproduct of fungal fermentation of a carbohydrate substrate<sup>17</sup>, it fits the definition of “nonsynthetic” and will be classified as such rather than “agricultural,” defined as “[a]ny agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock ...”.

Comments were received which argued both that pullulan could and could not be certified under the USDA organic regulations. These comments offer differing interpretations of whether any of the manufacturing processes would result in a product which would be certifiable. AMS will maintain the requirement that nonorganic pullulan

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<sup>16</sup> NOP 5033 – Classification of Materials: <https://www.ams.usda.gov/sites/default/files/media/NOP-5033.pdf>

<sup>17</sup> Pullulan Technical Report, September 7, 2018: <https://www.ams.usda.gov/sites/default/files/media/PullulanTechnicalReportFinal09072018.pdf>

be used only in “made with” products, as we are aware there are certified organic pullulan products on the international market.

This final rule adds pullulan to the National List as a nonagricultural ingredient. AMS notes that similar National List substances produced by microbial fermentation are classified as nonagricultural (e.g., citric acid, xanthan gum, and gellan gum). AMS agrees with NOSB determination that pullulan is a nonagricultural substance, as described in our response to comments regarding classification. The classification of pullulan as nonagricultural does not preclude the production of certified organic pullulan, as long as the process meets the requirements of § 205.105 and § 205.301.

*Genetically modified organisms.* A comment was opposed to the addition of pullulan to the National List because of the potential that genetically modified organisms (GMOs) might be used in the production of pullulan (e.g., substrates as nutrient sources for the fermentation process).

AMS understands concerns regarding the use of genetically modified organisms in the production of National List materials. The USDA organic regulations (§ 205.105) include a prohibition on ingredients produced or handled with the use of excluded methods (including genetic engineering) as defined in § 205.2.

*Digestibility concern.* A comment cited a study comparing human digestion of pullulan to digestion of maltodextrin. AMS understands that NOSB considered the effects of slow digestion (including increased flatulence, as cited in the comment) and did not conclude these effects to be sufficiently detrimental to human health to disqualify the substance from addition to the National List per OFPA (7 U.S.C. 6518(m)).

*General opposition.* Two comments generally opposed changes to the National List and were opposed to the addition of pullulan. AMS notes that OFPA permits the use of specific synthetic substances (i.e., those on the National List) in organic production. OFPA describes the procedures for amending the National List and provides AMS and

NOSB with criteria and guidelines to consider in evaluating changes to the National List. These procedures were followed by NOSB and AMS, and this rule adds pullulan to the National List.

*General support.* Comments supporting the addition of pullulan cited its potential to be used as a vegetarian alternative for capsules used for oral supplements. These comments argued that while gelatin is on the National List and is used for capsules, it is an animal byproduct, which vegan and vegetarian consumers choose not to use. Another comment stated that gelatin-based capsules are not appropriate for many vegan and vegetarian supplement products and may cause issues among kosher and halal consumers.

AMS appreciates public engagement in the rulemaking process and agrees with the general support above which mirrors the recommendation by NOSB. AMS is moving forward with adding this substance to the National List as proposed.

### **Collagen gel casing (§ 205.605)**

#### **Final action**

This final rule amends the National List to add collagen gel as a casing to 7 CFR 205.605(b) as a nonorganic nonagricultural ingredient allowed in organic handling. The amendment will permit the use of nonorganic forms of collagen gel when organic collagen gel is not commercially available (i.e., not available in an appropriate form, quality, or quantity, as determined by the certifying agent in the course of reviewing the organic plan).<sup>18</sup> The final rule only permits nonorganic collagen gel as a casing. This final rule adds collagen gel casing to § 205.605(b) rather than to § 205.606, as proposed. The change in AMS' classification of collagen gel (and, therefore, its location on the National List) is discussed in the "Comments Received and AMS' Response" section below.

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<sup>18</sup> See 7 CFR 205.606 and 7 CFR 205.2 for definition of "Commercially available."

AMS is finalizing the addition of collagen gel casing to the National List, as proposed by NOSB, as organic collagen gel is not commercially available as of the issuance of this final rule. This conclusion is based on AMS' review of comments made to NOSB and comments received in response to the proposed rule. Additionally, AMS searched the Organic Integrity Database and found no certified organic operations with certified organic collagen gel.<sup>19</sup>

AMS expects that the allowance for nonorganic forms of collagen gel when organic forms are not available will encourage organic certification of products that have not been previously eligible for organic certification. This will encourage food manufacturers to develop new organic products, which could, in turn, create new demand for organic production (livestock production). There are no alternatives on the National List which are suitable for use in a co-extrusion system as a non-removable edible film.

Collagen gel is described as a multi-ingredient product made from collagen (3.0 – 4.5%), cellulose (<3.0%), and water (95.5 – 97.0%) in the commissioned third-party technical evaluation report.<sup>20</sup> Collagen is isolated from animal materials (e.g., skin, bones) through thermal, acid, base, or enzymatic hydrolysis. Once isolated, the extract is decalcified and swollen with acid (generally hydrochloric or sulfuric) prior to use in a co-extrusion process.

When used in sausage production, collagen gel is used to enrobe the extruded product. The collagen gel forms an edible film that holds the form of the product and acts as a protective barrier. The collagen casing is an ingredient in the final product (i.e., it is disclosed on the ingredients list). AMS understands that collagen gel may be formulated with additional substances to improve the appearance (e.g., colors) or flavor of the final

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<sup>19</sup> Available at <https://organic.ams.usda.gov/Integrity/Default.aspx>. Accessed and searched for “collagen gel” on February 1, 2021.

<sup>20</sup> Collagen gel technical evaluation report, January 28, 2019: <https://www.ams.usda.gov/sites/default/files/media/CollagenGelGelatinCasingsTechnicalReport01282019.pdf>.

product. AMS expects these additional substances, when used, will be evaluated by USDA-accredited certifying agents for compliance with the National List and the USDA organic regulations.

AMS concluded that the addition of collagen gel to the National List is consistent with the requirements of OFPA sec. 6517(c). Namely, the substance is not harmful to human health or the environment; is necessary to production because of the unavailability of wholly natural substitute products; and is consistent with organic farming and handling. The amendment is made following the procedures established in OFPA (sec. 6517(d)).

### **NOSB review and recommendation (collagen gel)**

NOSB submitted a recommendation to AMS in April 2019 to add collagen gel to the National List.<sup>21</sup> NOSB recommendation followed receipt of a petition to add the substance to the National List in February 2018.<sup>22</sup> In NOSB's evaluation of the petition, they considered information from a third-party technical evaluation report and comments from the public. NOSB discussed the petition to amend the National List in subcommittee calls and at its public meetings in October 2018 and April 2019.<sup>23</sup>

In its recommendation, NOSB concluded that adding collagen gel to the National List was consistent with OFPA criteria (sec. 6518(m)). In its recommendation, NOSB noted that adding collagen gel to the National List would increase opportunity for production of organic products that are not possible with current ingredients on the National List, such as single-species sausage and meat products.

### **Comments received and AMS' response (collagen gel casing)**

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<sup>21</sup> NOSB final recommendation for collagen gel, April 26, 2019: <https://www.ams.usda.gov/sites/default/files/media/HSCollagenGelApr2019FinalRec.pdf>.

<sup>22</sup> Collagen gel petition: <https://www.ams.usda.gov/sites/default/files/media/CollagenGelPetition.pdf>.

<sup>23</sup> Written and oral public comments submitted for the October 2018 and April 2019 NOSB meetings are available at <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-st-paul-mn> and <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-seattle-wa>.

*Classification.* In the proposed rule, AMS requested additional information on whether the use of acid induces chemical change(s) in the collagen gel which should cause the substance to be classified as a nonagricultural, synthetic substance. In response, AMS received a comment stating that AMS guidance<sup>24</sup> indicates that synthetic acids used in a hydrolysis process would result in a synthetic product. The comment also stated that under this interpretation of program guidance, the use of synthetic acids as described in the technical evaluation report<sup>25</sup> would not be allowed in the production of nonsynthetic collagen gel.

Some comments received were neutral, neither in support of nor in opposition to the addition of collagen gel casing. One comment supported classifying collagen gel casing as an agricultural substance should it be added to the National List. This same comment also acknowledged that collagen gel casing's classification as an agricultural substance could be challenged during future NOSB meetings. However, the comment also stated that since the source material for collagen gel casing source is agricultural, its inclusion on § 205.606 would be appropriate.

Upon further review of the manufacturing process of collagen, as described in the petition and technical evaluation report, AMS agrees with the comment that the acid hydrolysis step typical in the manufacturing process of collagen is a non-biological chemical change that results in its classification as a nonagricultural, synthetic substance. In order to preserve the intent of NOSB to encourage future availability of certified organic collagen gel, AMS is listing collagen gel casing as a synthetic nonagricultural substance at § 205.605(b) with the annotation "may be used only when organic collagen gel is not commercially available."

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<sup>24</sup> AMS National Organic Program Handbook, Guidance NOP 5033-1 Decision Tree for Classification of Materials as Synthetic or Nonsynthetic, December 2, 2016.  
<https://www.ams.usda.gov/sites/default/files/media/NOP-Synthetic-NonSynthetic-DecisionTree.pdf>.

<sup>25</sup> Collagen gel technical evaluation report, January 28, 2019:  
<https://www.ams.usda.gov/sites/default/files/media/CollagenGelGelatinCasingsTechnicalReport01282019.pdf>.

AMS understands that there are many different manufacturing processes for the production of collagen gel<sup>26</sup>. It is our understanding that while there are many different processes for manufacturing collagen gel, the current predominant manufacturing process renders the final collagen gel as synthetic. While the main manufacturing process results in a synthetic product, there are manufacturing processes described which would result in a nonsynthetic product and are consistent with § 205.270 (i.e., could be a certifiable process). Aware of the fact that the addition of collagen gel to the National List would allow for the production of additional organic products, we classified collagen gel as synthetic due to the predominant manufacturing process to provide access to organic producers. Given that there are processing methods which could be certified, we are maintaining the commercial availability requirement to encourage the development of nonsynthetic, certified organic products.

*General Opposition.* AMS received comments opposed to adding collagen gel casing to the National List. Some of the opposing comments want organic products to be composed only of organic ingredients. AMS notes that OFPA permits the use of specific nonorganic substances (i.e., those on the National List) in organic production and handling. OFPA describes the procedures for amending the National List and provides AMS and NOSB with criteria and guidelines to consider in evaluating changes to the National List. These procedures were followed by NOSB and AMS, and this rule adds collagen gel to the National List.

*Misleading to Consumers.* A comment argued AMS will confuse consumers, especially vegan consumers, should collagen gel casings be allowed for use in organic plant-based sausage products. AMS understands that labeling requirements implemented by other agencies would require disclosure of collagen casings in a product's ingredient

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<sup>26</sup> Collagen Gel Technical Report, January 28, 2019:  
<https://www.ams.usda.gov/sites/default/files/media/CollagenGelGelatinCasingsTechnicalReport01282019.pdf>

list. AMS believes that disclosure of the collagen casing as an ingredient provides sufficient transparency for consumers.

### **III. Related Documents**

AMS published notices in the Federal Register on August 9, 2018, announcing the Fall 2018 NOSB Meeting (83 FR 39376) and on November 26, 2018, announcing the Spring 2019 NOSB meeting (83 FR 60373). These notices invited public comments on NOSB recommendations addressed in this final rule. The AMS proposed rule that preceded this final rule was published on June 8, 2020 (85 FR 35011).

### **IV. Statutory and Regulatory Authority**

OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by NOSB. Sections 6518(k) and 6518(n) of OFPA authorize NOSB to develop recommendations for submission to the Secretary to amend the National List and establish a process by which persons may petition NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. Section 205.607 of the USDA organic regulations permits any person to petition to add or remove a substance from the National List and directs petitioners to obtain the petition procedures from USDA. The current petition procedures published in the Federal Register (81 FR 12680; March 10, 2016) for amending the National List can be accessed through the NOP Program Handbook on the NOP website at [https://www.ams.usda.gov/rules-regulations/organic/handbook\\_](https://www.ams.usda.gov/rules-regulations/organic/handbook_)

#### **A. Executive Order 12866 and Regulatory Flexibility Act**

This final rule has been determined to be not significant for purposes of Executive Order 12866, and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that

would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS) to delineate which operations qualify as small businesses.<sup>27</sup> SBA has classified small agricultural producers that engage in crop and animal production as those with average annual receipts of less than \$1,000,000 (13 CFR 121.201). Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific type of manufacturing. Certifying agents fall under the NAICS subsector, “all other professional, scientific, and technical services.” For this category, the small business threshold is average annual receipts of less than \$16.5 million.

*Producers.* AMS has considered the economic impact of this final rulemaking on small agricultural entities. Data collected by USDA’s National Agricultural Statistics Service (NASS) and NOP indicate most of the certified organic production operations in the United States would be considered small entities. According to the 2019 Census of Agriculture, 16,585 organic farms in the United States reported sales of organic products and total farmgate sales more than \$9.9 billion.<sup>28</sup> Based on that data, organic sales

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<sup>27</sup> Table of Small Business Size Standards Matched to North American Industrial Classification System Codes, August 19, 2019: [https://www.naics.com/wp-content/uploads/2017/10/SBA\\_Size\\_Standards\\_Table.pdf](https://www.naics.com/wp-content/uploads/2017/10/SBA_Size_Standards_Table.pdf)

<sup>28</sup> U.S. Department of Agriculture, National Agricultural Statistics Service. 2019 Census of Agriculture. [https://www.nass.usda.gov/Publications/AgCensus/2017/Online\\_Resources/Organics/ORGANICS.pdf](https://www.nass.usda.gov/Publications/AgCensus/2017/Online_Resources/Organics/ORGANICS.pdf)

average just under \$600,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$1,000,000 sales threshold to qualify as a small business.

*Handlers.* According to the NOP's Organic Integrity Database, there are 19,059 organic handlers that are certified under the USDA organic regulations.<sup>29</sup> The Organic Trade Association's 2020 Organic Industry Survey has information about employment trends among organic manufacturers. The reported data are stratified into three groups by the number of employees per company: fewer than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector and the lower bound (50) of the range for the larger manufacturers is significantly smaller than SBA's small business thresholds (500 to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

*Certifying agents.* SBA defines "all other professional, scientific, and technical services," which include certifying agents, as those having annual receipts of less than \$16,500,000 (13 CFR 121.201). There are currently 77 USDA-accredited certifying agents, based on a query of NOP certified organic operations database, who provide organic certification services to producers and handlers. While many certifying agents are small entities that would be affected by this proposed rule, we do not expect that these certifying agents would incur significant costs as a result of this action as certifying agents already must comply with the current regulations (e.g., maintaining certification records for organic operations).

AMS does not expect the economic impact on entities affected by this rule to be significant. The effect of this final rule will allow the use of three additional substances in organic crop production and organic handling. Adding three substances to the National

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<sup>29</sup> Organic Integrity Database: <https://organic.ams.usda.gov/Integrity/>. Accessed February 1, 2021.

List will increase regulatory flexibility and provide small entities with more options to use in day-to-day operations.

**B. Executive Order 12988.**

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect. Accordingly, to prevent duplicative regulation, states and local jurisdictions are preempted under OFPA from creating programs of accreditation for private persons or state officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of OFPA. States are also preempted under sections 6503 through 6507 of OFPA from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of OFPA.

Pursuant to section 6507(b)(2) of OFPA, a State organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the State and for the certification of organic farm and handling operations located within the State. Such additional requirements must (a) further the purposes of OFPA, (b) not be inconsistent with OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to § 6519(c)(6) of OFPA, this final rule does not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056), concerning meat, poultry, and egg products,

respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

### **C. Paperwork Reduction Act.**

No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

### **D. Executive Order 13175**

This final rule has been reviewed under Executive Order 13175 – Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on: (1) policies that have tribal implication, including regulation, legislative comments, or proposed legislation; and (2) other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

AMS has assessed the impact of this final rule on Indian tribes and determined that this rule would not have tribal implications that require consultation under Executive Order 13175. AMS hosts a quarterly teleconference with tribal leaders where matters of mutual interest regarding the marketing of agricultural products are discussed. Information about the proposed changes to the regulations will be shared during an upcoming quarterly call, and tribal leaders will be informed about the proposed revisions to the regulation and the opportunity to submit comments. AMS will work with USDA's Office of Tribal Relations to ensure meaningful consultation is provided as needed with regards to the NOP regulations.

## **E. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

## **G. General Notice of Public Rulemaking**

This final rule reflects recommendations submitted by NOSB to the Secretary to add three substances to the National List.

## **List of Subjects in 7 CFR Part 205**

Administrative practice and procedure, Agricultural commodities, Agriculture, Animals, Archives and records, Fees, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205 is amended as follows:

## **PART 205—NATIONAL ORGANIC PROGRAM**

1. The authority citation for part 205 is revised to read as follows:

**Authority:** 7 U.S.C. 6501–6524.

2. Amend § 205.603 by redesignating paragraphs (b)(8) through (b)(11) as paragraphs (b)(9) through (b)(12) and adding paragraph (b)(8) to read as follows:

### **§ 205.603 Synthetic substances allowed for use in organic livestock production.**

\* \* \* \* \*

(b) \* \* \*

(8) Oxalic acid dihydrate—for use as a pesticide solely for apiculture.

\* \* \* \* \*

3. Amend § 205.605 by:

- a. In paragraph (a), adding in alphabetical order the term “Pullulan;” and

- b. In paragraph (b), adding in alphabetical order the term “Collagen gel.”

The additions read as follows:

**§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”**

\* \* \* \* \*

(a) \* \* \*

Pullulan—for use only in tablets and capsules for dietary supplements labeled “made with organic (specified ingredients or food group(s)).”

\* \* \* \* \*

(b) \* \* \*

Collagen gel—as casing, may be used only when organic collagen gel is not commercially available.

\* \* \* \* \*

Erin Morris, Associate Administrator,  
Agricultural Marketing Service.

[FR Doc. 2021-13323 Filed: 6/24/2021 8:45 am; Publication Date: 6/25/2021]